INNOVATIVE SUPPORT FOR PATIENTS WITH SARS COV-2 INFECTIONS REGISTRY (INSPIRE)

Rush University
University of Washington
Yale University
on behalf of the INSPIRE consortium
Disclosure

• Harlan M. Krumholz is co-founder of Hugo Health; Wade Schulz is a consultant to Hugo Health; Dave Hutten is the Product Lead at Hugo Health; Deb Chromik is a consultant to Hugo Health.
Participants

Speakers:
Harlan M. Krumholz MD. Harold H. Hines Jr. Professor of Medicine), Yale University
Bala Hota MD. Professor of Internal Medicine (Infectious Disease), Rush University
Graham Nichol, MD. Medic One Foundation Chair for Pre-hospital Emergency Care, UW

Other Panelists:
Jacqueline Rollin, Administrative Fellow, Rush University Medical Center
Wade Schulz, MD, PhD. Assistant Professor of Laboratory Medicine
Matthew J. Thompson, MB, ChB, DPhil, Helen D. Cohen Professorship in Family Medicine, UW
Deb R. Chromik, Participant Experience, Hugo Health
Dave Hutton, Product Lead, Hugo Health
New reported cases by day in the United States
But...

Inadequate information
The Need

Rapid knowledge generation

Actionable insights
Ten Weeks to Crush the Curve

Harvey V. Fineberg, M.D., Ph.D.

6. Learn while doing through real-time, fundamental research. Clinical care would be vastly improved by effective antiviral treatment, and every plausible avenue should be investigated. We did it with HIV; now, we need to do it faster with SARS-CoV-2. Clinicians need better predictors of which patient’s condition is prone to deteriorate rapidly or who may go on to die. Decisions to shape the public health response and to restart the economy should be guided by science.
### Types of Evidence Needed for Controlling an Epidemic

<table>
<thead>
<tr>
<th>Evidence Needed</th>
<th>Study Type</th>
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<tbody>
<tr>
<td>No. of cases, including milder ones</td>
<td>Syndromic surveillance plus targeted viral testing</td>
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<tr>
<td>Risk factors and timing of transmission</td>
<td>Household studies</td>
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<tr>
<td>Severity and attack rate</td>
<td>Community studies</td>
</tr>
<tr>
<td>Severity “pyramid”</td>
<td>Integration of multiple sources and data types</td>
</tr>
<tr>
<td>Risk factors for infection and severe outcomes, including death</td>
<td>Case–control studies</td>
</tr>
<tr>
<td>Infectiousness timing and intensity</td>
<td>Viral shedding studies</td>
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</table>
Focus

• Risk-stratification of patients
• Platform to rapidly test diagnosis, therapeutics and back to work strategies - and support life sciences
Key Outcomes

• Hospitalizations, acute care visits, symptom burden, health status, death
Need...

• Address the mechanics... how?
Properties of the solution

• Rapid deployment
• Timely, fit-for-use data
• Participant-centric
• Trustworthy
• Low-burden on clinical teams
• Standards-based, flexible approach
• Remote as possible
• Private, secure
• Collaborative
• Regulatory-compliant
• Reusable
• Pluripotent
Philosophy

• Participants as part of the team; involved, engaged, respected; with agency over their data.
Solution

• Rapidly deployed, digitally enabled, participant centered platform to collect longitudinal data and facilitate observational and experimental studies.
“... Working Group envisions an adaptation of download-and-forward capability as a “Sync for Science” application & protocol that enables participants to acquire & review their EHR data... to detect & forward clinical data as new medical events occur, full implementation of the S4S concept will require coordinated action by federal agencies...”
Data accessible to researchers & clinicians through dashboards, local applications, & integrations with existing databases and systems

People authorize collection of their data with Hugo

People authorize data sharing

Data normalized—improved integrity, ready for analysis

Data harmonized—digital de-duplication, automated term/ontology mapping, multi-site integration

People can view their data with the mobile app

Clinical Records

Pharmacies

Payors

Surveys

Devices/Wearables
Aggregating Multiple Real-World Data Sources using a Patient-Centered Health Data Sharing Platform: an 8-week Cohort Study among Patients Undergoing Bariatric Surgery or Catheter Ablation of Atrial Fibrillation

Sanket S. Dhriva1, Joseph S. Ross2,3,4, Joseph G. Akar2,3, Brittany Caldwell5, Karla Childers2, Wing Chow1, Laura Giacol0, Paul Coplan2, Jun Dong6, Hayley J. Dykhoff7, Stephen Johnston7, Todd Kellogg2, Cynthia Long9, Peter A. Noseworthy10,11, Kurt Roberts11, Anindita Saha8, Andrew Yoo1, Nilay D. Shah12

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Fig. 9

Pharmacy Data
- Prescription names
- Prescription source (CVS/Walgreens/Telekinect)
- Formulations and dosages
- National Drug Code (NDC)
- Start and end date
- Number of refills available
- Prescriber

Electronic Health Record Data
- Encounters
- Encounter location
- Encounter diagnoses
- Labs and lab results
- Imaging tests
- Medications
- Procedures
- Problem list

Personal Digital Device Data
- Activity, including ambulation and sleep (Fitbit)
- Weight (withings scale)
- Single Lead ECG (Kardia Mobile)

Patient Reported Outcome Measures (PROMs)
- Short mobile-friendly questionnaire emailed twice weekly for 10 total times immediately post-procedure
- Longer questionnaires emailed at baseline, 1, 4, and 8 weeks post-procedure
- Email reminder instituted during study
Full Title: Use of mobile health apps in low-income populations: a prospective study of facilitators and barriers

Short Title: Liu; Use of mHealth apps in low-income populations

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Approach

- Prototype site
- Scaling strategy
Rush University Medical Center

• 669 bed academic medical center
• 35,000 admissions per year
• 65,000 ED visits per year

• **Clinical Staff**
  • ~1400 professional nursing staff
  • ~800 attending physicians
  • ~650 residents and fellows

• **Ambulatory Practices**
  • ~50 owned practices and ~100 private practices

• **Epic 2018 EHR**
Timeline

-March 2: Hospital Incident Command Established
-March 4: First COVID + Patient seen at Rush
-March 6: Rush Research Teams Activated
-March 9: Registry Protocol submitted to IRB
-March 13: Protocol Approved
-March 19: Biorepository Protocol Protocol Approved
-March 23: Hospital Surge Plan Activated
-March 27: Enrollment Begins
-March 28: Surge Begins
### Patient Characteristics

<table>
<thead>
<tr>
<th>Patient Characteristics - Rush</th>
<th>Overall</th>
<th>Admitted</th>
<th>ICU</th>
<th>Vent</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Known Covid-19 + Patients</strong></td>
<td>466</td>
<td>111</td>
<td>52</td>
<td>33</td>
</tr>
<tr>
<td>Male</td>
<td>50%</td>
<td>59%</td>
<td>71%</td>
<td>67%</td>
</tr>
<tr>
<td>Mean Age, yr</td>
<td>48</td>
<td>57</td>
<td>58</td>
<td>58</td>
</tr>
<tr>
<td><strong>Race</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>African American</td>
<td>50%</td>
<td>56.6%</td>
<td>48%</td>
<td>42%</td>
</tr>
<tr>
<td>White</td>
<td>25%</td>
<td>16%</td>
<td>19%</td>
<td>18%</td>
</tr>
<tr>
<td>Asian</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>Other</td>
<td>22%</td>
<td>27%</td>
<td>33%</td>
<td>39%</td>
</tr>
<tr>
<td>Hispanic Ethnicity</td>
<td>16%</td>
<td>24%</td>
<td>23%</td>
<td>36%</td>
</tr>
</tbody>
</table>

To date: 1159 PUIs; 466 COVID+; 111 admitted
Enrollment Workflow

- Identify Patients in COVID-19 Dashboard
- Upload in REDCap
- Call Patients discuss Interest in Study
  - No (STOP)
    - Maybe
      - Leave Study Information & re-approach
    - Yes
      - Tele-Enroll with HUGO Platform
        - Pt. Provides full name, email address and creates password
          - Print consent from Hugo CRC sign, PI sign and place in chart
            - Log in and sign consent
Rush University Medical Center is hoping you will join us in our effort to better understand the experience of people with COVID-19 symptoms. We are working as fast as we can to improve outcomes for everyone by learning as much as we can from each person who is under our care. Your contribution will make a difference.

To participate, we ask that you use the button above to create an account with Hugo Health, the company we choose to enable you to collect your health data and share it with our research team. Hugo was created to empower people with their health data and does not do anything with your data without your permission - details are available in their Privacy Center. Hugo will allow you to link your health system and pharmacy data and receive study related surveys by email or text. Your Hugo Health account will be yours to keep and use indefinitely and free of charge.
Interoperability for Scalable Registries

- Standards-based acquisition and data transfer
  - FHIR
  - CCDA
- Portal based authentication
  - OAUTH2
  - Credentials Based
- Minimal IS implementation time
Recruitment Best Practices

• Provider Engagement – include attending physician staff

• Electronic consent provides optimal workflow

• Initial consent workflow technically feasible using telephone

• Remote consent is possible
Graham Nichol, MD
Catchment Population > 20 M

>1 M Emergency Department Visits

>2 M Outpatient Visits

Additional Locations, Sites Based on Interest and Funding
Rapidly and Precisely Answer Clinically Relevant Questions

- Clinical epidemiology
- Support for life sciences
- Predictive analytics
- Evaluation of diagnostics & therapeutics
- Evaluation of back to work strategies
Discussion

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